

### **REMARKS**

In the December 29, 2003 Final Office Action, of pending claims 1-31 and 33-34, claims 1-27 were withdrawn as being directed to a non-elected invention; claims 28, 30-31, 33-34, and 36-44 were rejected; and claims 29 and 35 were objected to.

By the present amendment, claims 28, 31, 33-37, 39-40, 42-43 are amended; claim 38 is canceled; withdrawn claims 1-27 are canceled; and new claims 45-52 have been added; leaving claims 28-31, 33-37, and 39-52 pending in the application with claims 28, 37, and 45 being independent. Applicant respectfully requests reexamination of this application and entrance of this Amendment, and submits that no new matter has been added.

In summary, as stated above, claim 38 is canceled. The subject matter of claim 38 is incorporated into independent claim 37. Therefore, the 35 U.S.C. 102 (b) rejections citing Reynolds and Nigam '946 are obviated, since claim 38 was not rejected by either reference in the Final Office Action. Thus, in light of the claim amendment, the only remaining relevant reference is U.S. Patent Publication No. 6,102,946 to Nigam; however, as noted below, Nigam does not render amended claim 37 unpatentable.

Moreover, independent claim 28 and dependent claims 30, 31, and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,655,774 to Choyce. The rejections of the Final Office Action are respectfully traversed. In summary, Nigam '946 fails to disclose, teach, or suggest "a removable sheet" having "removable" markings. Choyce fails to disclose, teach, or suggest, "a removable pliable sheet" or "a removable, transparent, pliable sheet." Therefore, these references neither anticipate nor render obvious the claimed invention. Each rejection is discussed in detail below.

In addition, the foregoing amendments to the claims obviate or render moot the rejections under 35 U.S.C. § 101, 102(e), 103(a), and 112 second paragraph. Furthermore, since the Action merely revises the basis of the prior art rejection from 35 U.S.C. 102 to 35 U.S.C. 103, the finality of the Action is improper.

Accordingly, the finality of the Final Office Action mailed on December 29, 2003 should be withdrawn and the present application should be passed to issue. If the rejections are maintained, Applicant submits that this Amendment was not presented at an earlier date in view of the fact that Applicants are responding to a new ground of rejection set forth in the Final Office Action. In accordance with the requirements of 37 CFR 1.116, Applicant respectfully requests entry and consideration of the foregoing amendments as they remove issues for appeal, address matters directed toward form, or place the application in condition for allowance.

**Reconsideration of Final Rejection (Withdrawal of, Premature MPEP 7.06.07(d))**

Applicant respectfully requests reconsideration of the finality of the last Office Action. The Final Office Action, rejects claims 28, 32-33 as being unpatentable over U.S. Patent No. 4,655,774 to Choyce. The Office Action sets forth new grounds for rejection of the claims and raises new issues to which Applicant is entitled to a full and fair hearing as set forth in section 706.07 of the MPEP. Furthermore, Applicant's claim amendments were not the reason for modification of the rejection from a 35 U.S.C. § 102 rejection to a 35 U.S.C. § 103 rejection, and thus did not necessitate the final rejection.

In the First Office Action, claims 28, 32-33, 37-38, and 43 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,655,774 to Choyce. In the action, Choyce was interpreted as disclosing all of the elements of independent claim 28 and dependent claim 32. Applicant traversed this rejection; however, claim 28 was amended to incorporate the language of claim 32- - specifically, language reciting that the removable sheet being "pliable." The

amendment was not made in response to the rejection, since the rejection stated that Choyce did in fact disclose a pliable sheet.

Subsequently, in the Final Rejection, the Office Action admits that Choyce did not disclose a pliable sheet or applicator. The Final Office Action alleged new grounds for rejection, while only altering the interpretation of the base reference. The Final Office Action stated that claim 28, as amended, was unpatentable over Choyce in view of being an obvious design choice. This modification constitutes new grounds for rejection and raises two new issues to which Applicant is entitled a full and fair hearing as set forth in section 706.07 of the MPEP.

First, it is unclear whether Official Notice is being relied upon. If Official Notice is the basis of the rejection, Applicant has a right to traverse the Official Notice and request evidence to substantiate the alleged motivations to modify. Second, the Office Action cites In Re Leshin, 125 USPQ 416, as legal support for the design choice. As pointed out in MPEP 2144.04, such legal precedent may only be relied upon if the facts in the legal decision are sufficiently similar to those in the application under examination. As will be discussed in more detail later in the arguments section of this amendment, the facts of the instant case and In Re Leshin are not sufficiently similar as required by MPEP 2144.04.

Therefore, the Finality of the previous Office Action should be removed, as a clear issue has not surfaced for appeal. Applicant requests that the amendments be entered and arguments concerning the new grounds for rejection and new issues raised be fully considered.

#### **Claim Rejections – 35 U.S.C. § 101**

Claims 34 and 42 stand rejected under 35 U.S.C § 101 as being directed to non-statutory subject matter. These claims have been amended to avoid each of the above rejections raised in the Office Action. The allegedly positively recited non-statutory subject matter has been revised or removed to more clearly recite “portions of the body” as only part of intended use claim language.

Accordingly, the pending claims no longer are believed to be drawn to alleged non-statutory subject matter and comply with the requirements of 35 U.S.C § 101.

**Claim Rejections – 35 U.S.C. 112 2<sup>nd</sup> paragraph**

Claims 36 and 37-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. These claims have been amended or canceled to avoid each of the objections raised in the Office Action. All terminology is clear. The terminology alleged to be unclear is omitted or revised.

Accordingly, the pending claims are definite and comply with the requirements of 35 U.S.C. § 112.

**Rejections Under 35 U.S.C. §102(e) and 103(a)**

*A. U.S. Patent Application Pub. No. US 2002/0029981 to Nigam*

Claims 37, 38 and 41-42 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Pub. No. US 2002/0029981 to Nigam. The Office Action alleges that the Nigam Publication discloses all of the elements of the claims.

In amended claim 37, Applicant claims an inlay for correcting refractive error in the cornea of the eye. The inlay has first and second surfaces. One of the first and second surfaces has at least one removable marking for aligning with a corresponding marking on the cornea. Furthermore, independent claim 37 has been amended to recite that the **marking** is disposed on a **removable sheet** of material directly overlying the second surface.

Contrary to the Office Action, the Nigam Publication '981 does not disclose, teach or suggest all of the elements of amended independent claim 37. Anticipation requires that every limitation of a claim must identically appear in the prior art reference. See Gechter v. Davidson, 43 U.S.P.Q.2d 1030, 1032 (Fed. Cir. 1997). Specifically, the Nigam Publication '981 does not disclose, teach or suggest the limitation "*at least one removable marking...said at least one*

*removable marking being disposed on a removable sheet of material directly overlying the second surface.”*

In contrast, the Nigam Publication ‘981 discloses a tool 30 having an applicator 45. The applicator has apertures for facilitating alignment. The applicator has an arcuate surface 42, which matches that of the cornea, thus enabling the implant to be more evenly deposited on the corneal surface. (page 4, paragraphs 0049 and 0055). The removable markings of the Nigam Publication ‘981 are on the inlay, **not on the removable sheet**. Lastly, Applicants submit that it also would not have been obvious to modify the Nigam Publication ‘981 applicator 45 to include removable markings. The applicator 45 utilizes apertures integral with the applicator and thus cannot be removed and the prior art discloses no motivation to do so.

Therefore, Applicant submits that amended independent claim 37 and its dependent claims 39-44 are allowable. Moreover, certain dependent claims recite additional features that further distinguish them from the cited reference. For example, claim 39 recites that the markings on the removable sheet are at least ten radial axes extending from about the center of the inlay in a direction of the periphery of the inlay. Claim 40 recites that the markings on the removable sheet include radial markings and are adapted to align with a positioning tool to facilitate proper positioning of the inlay on the exposed surface of the cornea. Claim 43 was indicated as containing allowable subject matter. Claim 44 is was indicated as containing allowable subject matter.

Claims 39-40 also were rejected 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Pub. No. US 2002/0029981 to Nigam.

Applicant submits that it would not have been obvious to modify the Nigam Publication ‘981 markings. In the Action, “Official Notice” is apparently taken that it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the apertures of the Nigam Publication ‘981 to a pattern similar to Applicant’s radial pattern extending from a center point, since they are functional equivalents.

However, no motivation is established by any evidence of the record to show why one of ordinary skill in the art would undertake this modification. The Nigam applicator tool utilizes an aperture for aligning the visual axis. Applicant's radial pattern is utilized so the removable sheet and inlay can line up on top of one another for ensuring proper inlay orientation. The Nigam Publication '981 device functions in totally different manner. Although the alleged "marks" taught by the Nigam application, openings 23 and 22, for example, are used for assisting in alignment, they are clearly not aligned with corresponding markings on the cornea or the inlay. As noted on page 4, para. 0049 of the Nigam Application, the central opening 23 uses the pupil diameter to assist in alignment. There is no teaching or suggestion that any portion of the eye could be marked with a mark that corresponds to a removable marking on a removable sheet of an inlay that extends along at least one radial axis of the inlay surface.

If Official Notice is being utilized to support the rejection, Applicant respectfully traverses the Official Notice taken and requests evidence to substantiate the alleged motivations to modify Nigam Publication '981 as required under MPEP 2144.03. None of the prior art of record discloses that it is well known in the art to modify a tool applicator to include a radial pattern extending from a center point, and such unsupported allegation cannot be used to reject the claims. Thus, the requirements of a proper prima facie case of obviousness have not been met.

*B.      U.S. Patent No. 4,655,774 to Choyce*

Claims 28, 30, 31, and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,655,774 to Choyce. However, claims 29 and 34-36 are indicated allowable if rewritten in independent form to overcome the rejections under 35 U.S.C. §101, 112 second paragraph.

As noted in amended independent claim 28, Applicant's inlay has a first surface for placement on an exposed surface of the cornea and a second surface opposite the first surface. Additionally, the inlay has a removable, **pliable, sheet** of material directly adjacent and

overlying the second surface for **conforming to the second surface**. Moreover, newly added independent claim 45 is substantially the same as independent claim 28, but also requires the removable sheet to be **transparent**.

As stated in the Office Action, the Choyce patent does not disclose, teach or suggest all of the elements of independent claims 28 and 45. Specifically, the Choyce patent does not disclose, teach or suggest a removable, **pliable** sheet of material directly adjacent the second surface of an inlay, such that the sheet also overlies and **conforms to** the second surface of the inlay, as recited in independent claims 28 and 45. Moreover, newly submitted independent claim 45 also requires a **transparent** removeable sheet. Lastly, the Choyce patent also does not teach or suggest removable markings on a surface of the removeable sheet.

First, Choyce does not disclose a sheet. A sheet is commonly defined as a broad flat thin piece of a material, especially a rectangular piece of paper, metal, plastic, ice or glass. The rigid ring-shaped instrument of Choyce, even in light of the broadest reasonable interpretation, does not meet this limitation. Second, as recited in newly submitted claim 45, Choyce unequivocally does not disclose a transparent sheet. The Choyce ring-shaped instrument is a solid opaque piece of material having a center aperture.

There is no disclosure or suggestion that the Choyce instrument is pliable to conform to the surface of the inlay, and clearly the instrument is not directly adjacent the surface of the inlay. In fact, the instrument is specifically placed on the exterior surface of the cornea, and not directly adjacent the surface of the inlay.

Furthermore, it appears that the Office Action is relying upon Official Notice when modifying the ring-shaped instrument to be constructed of a pliable material. In support of the rejection, it is alleged, that it would have been obvious to one of ordinary skill in the art to reconstruct the rigid ring-shaped instrument of Choyce as a pliable sheet to prevent trauma to the eye.

However, no motivation is established by any evidence of the record to show why one of ordinary skill in the art would undertake this modification. In fact, the modification of the instrument into a pliable sheet would render the device inoperative for its intended purpose of assisting with visual alignment. The circular ring is a solid opaque ring. If the ring was modified into a pliable sheet, there would be no aperture present for alignment.

If Official Notice is being utilized to support the rejection, Applicant respectfully traverses the Official Notice taken and requests evidence to substantiate the alleged motivations to modify Choyce as required under MPEP 2144.03. None of the prior art of record discloses that it is well known in the art to modify a rigidly shaped instrument into a pliable sheet and such unsupported allegation cannot be used to reject the claims.

Furthermore, in support of the proposed modification, the rejection is apparently using the terms “design choice” and “well known” to conduct a piecemeal reconstruction of the Choyce reference without providing any motivation to combine. Thus, the requirements of a proper prima facie case of obviousness have not been met.

Moreover, the Office Action cites, In Re Leshin, 125 USPQ 416, as legal support for making the design choice. As pointed out in MPEP 2144.04, such legal precedent may only be relied upon if the facts in the legal decision are sufficiently similar to those in the application under examination. The applicant's invention in In Re Leshin was a combination of mechanical elements constituting a mechanism superficially resembling the common lipstick holder, except that the cosmetic body of sticklike form had a follower embedded in its lower end and was moved by turning a knob attached to the threaded stem that was disposed axially of and inside the stick of cosmetic. The applicant alleged that a double seal was the feature that made his main claim patentable. In the instant case, the Office Action alleges it would have been obvious to modify a rigid ring-shaped instrument, thus rendering the claim limitation “pliable sheet,” obvious. Clearly, the facts of the instant case and In Re Leshin are not substantially similar.

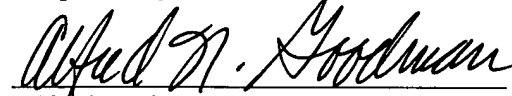


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Additionally, it would not have been obvious to modify the Choyce instrument so that it could be positioned directly adjacent the surface of the inlay, since it would be necessary to increase the size of the opening formed in the cornea. This would cause a greater intrusion into the cornea of the eye, which the Choyce disclosure indicates is a problem with the prior art of kerato-prosthesis. Therefore, Applicant submits that independent claims 28 and 45, and their respective dependent claims 29-31, 33-36 and 46-52, are allowable.

Prompt and favorable action is solicited. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number listed below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Alfred N. Goodman", written over a horizontal line.

Alfred N. Goodman

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